

'15 STUDY EVALUATION TEMPLATE
Cost-Effectiveness Analysis (CEA)

Evaluator's Name:

Date of Evaluation:

Concept/BIQSFP Number and Title:

Instructions for BIQSFP Evaluators: You have been asked to provide an evaluation of the cost-effectiveness analysis (CEA) study associated with the Phase 3 concept listed above. Your responsibilities as an evaluator consist of evaluating the proposed study and completing this form with your written comments by filling out the fields that follow each review criterion. A copy of the **CEA Study Evaluation Guidelines** which includes the **Study Checklist for Phase 3 Clinical Trials with a Comparator Arm and CEA Component(s)** is attached for your review.

Please use the applicant's responses within the *BIQSFP Study Checklist*, *BIQSFP Study Application*, and *BIQSFP Budget* in completing your evaluation.

After completing this form please save it to a new file, attach the file to an e-mail message referencing the concept/BIQSFP number, and forward the email to the CTEP, DCP, or CCCT Program Staff responsible for sending this evaluation. Submit your response at least 3 business days preceding the concept evaluation conference call/meeting, so that all perspectives may be shared and your written comments viewed by other evaluators of this concept. You will likewise be provided access to the written comments of the other evaluators.

Criteria for Review and Prioritization of CEA Studies

1. The overall value-added of pairing CEA with this clinical trial

Strengths:

Weaknesses:

2. The potential of the CEA to influence clinical practice and decision-making

Strengths:

Weaknesses:

3. Appropriateness of the choice of intervention(s) and comparator (control arm) for the CEA

Strengths:

Weaknesses:

4. Choice of Outcome Measure(s) for the analysis

Strengths:

Weaknesses:

5. The appropriateness and feasibility of the data collection plan

Strengths:

Weaknesses:

6. The modeling component of the CEA (if appropriate)

Strengths:

Weaknesses:

7. The Uncertainty Analysis

Strengths:

Weaknesses:

8. It is not intended that any priority or particular level of merit be assigned to one of the previous criteria over another. Based on the totality of the information, the strength of the data presented, and your scientific judgment, is your level of enthusiasm for the study (*circle one*):

High

Mild

1

2

3

4

5

9. Please comment on the attached *BIQSFP Cost Estimate Worksheet(s)* and *Budget Justification*. Provide recommendations if needed.

It is understood that by agreeing to assist in this evaluation, you have no conflicts of interest with this concept. In addition, all unpublished information, reports, and discussions are strictly confidential.